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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation	No. 2:15-MD-02641-DGC

JOINT PROPOSED SUMMARY FOR PURPOSES OF SUGGESTION OF REMAND OF MATURE CASES

(Assigned to the Honorable David G. Campbell)

Pursuant to the Court's Order dated July 9, 2018 (Doc. 11774), the Parties submit the following joint proposed summary for purposes of the suggestion of remand of the ten mature cases in this multidistrict litigation proceeding ("MDL"). *See* Doc. 914-1 (listing mature cases).

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I. Introduction

On August 17, 2015, the Judicial Panel of Multidistrict Litigation ("JPML" or "Panel") designated this Court as the transferee court for all related federal actions arising out of the sale or use of inferior vena cava ("IVC") filters manufactured and marketed by Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard"). *See* Doc. 1.[1] Each of the designated cases listed on Exhibit A was transferred to this Court pursuant to that order. This MDL currently involves more than 4,000 personal injury cases against Bard.

The IVC is a large vein that returns blood to the heart from the lower body. An IVC filter is a small metal device implanted in the IVC to catch blood clots before they reach the heart and lungs. This MDL involves seven different generations of Bard's retrievable IVC filters – the Recovery®, G2®, G2® Express, G2®X, Eclipse®, Meridian®, and Denali®. They are spider-like devices that have multiple struts fanning out from a cone-shaped head. The "limbs" consist of "legs" with elastic hooks that attach to the IVC wall, and shorter curved "arms" that serve to catch or break up bloods clots. Each of these filters is a variation of its predecessor.

The Court entered an order on September 15, 2015, providing for an initial case management conference. *See* Doc. 72. Following the initial conference held on October 29, 2015, the Court identified ten "mature" cases included in the MDL that were sufficiently advanced to consider remanding them, but the parties agreed they should remain a part of the MDL and should not be remanded at that time. *See* Docs. 249, 363 (as amended by Doc. 1485). Following the second case management conference held on January 29, 2016, the Court and parties concluded that some or all of these cases may be ready for remand before other cases in the MDL proceeding. *See* Doc. 519. Thereafter, the Court regularly requested remand status updates for these mature cases. *See* Docs. 1319, 2238, 3214, 4311, 5770, and 8871. The parties indicated that remand should await completion of expert discovery

[1] All references to docket numbers are to the general docket for MDL 2641 (2:15-md-02641-DGC), unless otherwise specified.

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because such discovery may be relevant in the trials of the mature cases. *See* Doc. 3214 at 3. The Court agreed, concluding that "generic" expert disclosure and discovery, and any related *Daubert* motions, should be handled in this MDL. *See* Doc. 4311. Accordingly, the mature cases could not be remanded until any such *Daubert* motions were decided. *See* Doc. 5770 at 3.

The Court held a conference on June 1, 2018, and requested briefing from the parties addressing the appropriate time for remand of these mature cases. *See* Doc. 11320. The Court ultimately concluded on June 28, 2018, that it is time to remand these ten mature cases to their home districts. *See* Doc. 11659.

Accordingly, the Court will submit this Suggestion of Remand to the JPML to facilitate the prompt remand of the designated cases (those listed in Exhibit A) by the JPML to the transferor courts for further proceedings, including case-specific discovery, pre-trial motions practice, and final disposition. To assist transferor courts following remand of the cases listed in Exhibit A, this MDL Pretrial Order describes the events that have taken place to date in this MDL. A copy of this MDL Order, along with the case files and materials, will be available to the transferor courts.

II. Background

A. Case Management Orders

The primary orders governing the pretrial management of MDL 2641 are a series of Case Management Orders ("CMO"), along with certain amendments. These Orders are discussed in detail below. All of the CMOs in MDL 2641 can be found at the court's website at http://www.azd.uscourts.gov/case-info/bard.

B. Lead and Liaison Counsel

CMO No. 1, entered on October 30, 2015 (Doc. 248), appointed Co-Lead/Liaison Counsel for Plaintiffs to manage the litigation on behalf of Plaintiffs, and set out the responsibilities of Co-Lead/Liaison Counsel. Plaintiffs' Co-Lead/Liaison Counsel has changed since the inception of the MDL. Mr. Ramon Lopez, of Lopez McHugh, LLP, in

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Newport Beach, California, and Mr. Mark O'Connor, of Gallagher & Kennedy, P.A., in Phoenix, Arizona are now Co-Lead/Liaison Counsel. *See* Doc. 5285. Mr. Richard North of Nelson Mullins Riley & Scarborough, LLP, in Atlanta, Georgia, remains Defendants' Lead Counsel.

C. Plaintiffs' Steering Committee and Common Benefits Fund

CMO No. 1 also directed the selection and appointment of a Plaintiffs' Steering Committee ("PSC") to assist in the coordination of pretrial activities and trial planning. The Co-Lead/Liaison Counsel and the PSC together form the Plaintiffs Leadership Counsel ("PLC"). The PSC acts on behalf of, or in consultation with, Plaintiffs' Co-Lead/Liaison Counsel in the management of the litigation. The PLC assists all Plaintiffs in MDL 2641 by overseeing discovery, appearing before this Court, attending status conferences, and preparing motions and responses regarding case-wide discovery matters. CMO No. 1 was later amended to select and appoint a Plaintiffs' Executive Committee ("PEC") to assist the Co-Lead/Liaison Counsel in the administration, organization, and strategic decisions of the PLC. *See* Doc. 4016. The configuration of the PSC has changed during the course of the litigation. *See* Docs. 248, 4016, 5285.

CMO No. 6, entered on December 18, 2015 (Doc. 372), set rules, policies, procedures, and guidelines for costs and attorneys' fees incurred by attorneys acting for the common benefit of all Plaintiffs in MDL 2641.

D. Status Conferences

Since the inception of MDL 2641, the Court has held regular status conferences with Plaintiffs' Co-Lead/Liaison Counsel and Defendants' Lead Counsel to discuss issues related to the litigation. The initial case management conference was held in October 2015. At the initial conference, deadlines were set for, among other things, the filing of a master complaint, a master answer, a short-form complaint and answer, proposed profile forms, a proposed protective order (including Rule 502 provisions), a proposed protocol governing the production of Electronically Stored Information ("ESI"), as well as deadlines to

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complete first-phase MDL discovery and address privilege log issues. *See* Doc. 249.[2] Thereafter, the Court conducted status conferences approximately every 10 weeks to ensure that the parties were on task and to address routine discovery issues and disputes. In addition to the periodic status conferences, the Court conducted telephonic hearings to address time-sensitive issues, as well as numerous additional conferences to consider various matters, including hearings on dispositive motions and general case management issues.

E. Bellwether Trials

On May 5, 2016, the Court entered an Order (Doc. 1662) providing for the selection of Plaintiffs who would be subject to individual case-specific discovery and eligible to be part of the "bellwether" trial process. From that group, six Plaintiffs were ultimately selected for individual bellwether trials. *See* Docs. 5770, 11659. To date, the Court has presided over two bellwether trials: *Booker v. C. R. Bard, Inc., et al.*, No. CV-16-00474-PHX-DGC; and *Jones v. C. R. Bard, Inc., et al.*, No. CV-16-00782-PHX-DGC. A third, fourth, and fifth bellwether trial are currently set for trial in September 2018, February 2019, and May 2019. The Court has yet to determine whether a sixth bellwether trial should be held.

1. *Booker v. C. R. Bard, Inc., et al.*

The first bellwether trial, *Booker*, involving a Bard G2 IVC filter, resulted in a verdict in favor of Bard on Plaintiff's strict liability and negligent design, as well as strict liability failure-to-warn claims, but in favor of Plaintiff on her negligent failure-to-warn claim. The jury awarded compensatory damages against Bard in the amount of $1,600,000.00, and punitive damages in the amount of $2,000,000.00. The Court denied Bard's motion for judgment as a matter of law and Bard's motion for a new-trial. Bard has

[2] The mature cases listed in Exhibit A were not governed by the Master Complaint and Master Responsive Pleading, but continue to be governed by the complaints (including any amended complaints) and answers filed in the various transferor courts prior to transfer. *See* Doc. 363 (as amended by Doc. 1485). The parties were also relieved from preparing or exchanging profile forms in these particular cases. *See* Doc. 365 (as amended by Doc. 927).

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appealed to the United States Court of Appeals for the Ninth Circuit (No. 18-16349). Plaintiff Booker has cross-appealed (No. 18-16460).

2. *Jones v. C. R. Bard, Inc., et al.*

The second bellwether trial, *Jones*, involving a Bard Eclipse IVC Filter, resulted in a jury verdict in favor of Bard on Plaintiff's strict liability and negligent design, and strict liability and negligent failure-to-warn claims. To date, Plaintiff has not filed for post-trial relief. Plaintiff has appealed to the United States Court of Appeals for the Ninth Circuit (No. 18-16461).

3. *Kruse v. C. R. Bard, Inc., et al.*

The third bellwether trial, *Kruse*, was set for trial on September 18, 2018. Following review of Bard's motion for summary judgment, the Court determined that it must grant summary judgment in favor of Bard on the claims asserted by Plaintiff Kruse as barred by the statute of limitations. After conferring with the parties, the *Hyde v. C. R. Bard, Inc., et al.*, case was moved to the September 2018 bellwether slot in lieu of *Kruse*.

4. Other Scheduled Bellwether Trials

A fourth and fifth bellwether trial are currently set for trial in February 2019 and May 2019. The Court plans to try the *Tinlin v. C. R. Bard, Inc., et al.*, and *Mulkey v. C. R. Bard, Inc., et al.*, cases during these months. But the Court has yet to determine the order of the trials, and the dates for the trial in May. The Court has also yet to determine whether a sixth bellwether trial should be held.

III. Discovery

A. Generic Fact Discovery

Plaintiffs have conducted extensive fact discovery against Bard. All common fact discovery in these cases has now been completed. Therefore, transferor courts need not be concerned with facilitating general fact discovery on remand.

Prior to the establishment of this MDL, Plaintiffs had conducted substantial common discovery against Bard (including in the mature cases) concerning all aspects of Bard's IVC

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filters, including the design, testing, manufacturing, marketing, labeling, and post-market surveillance of these devices. Bard produced over 2.5 million pages of documents and ESI, responded to thousands of written discovery requests, and over 80 corporate witnesses depositions were taken. All of that pre-MDL general fact discovery was made available by Bard to all Plaintiffs in the MDL.

This MDL was formed to centralize all pretrial proceedings and finally complete all common fact and expert discovery concerning Bard's IVC filters. *See* Doc. 1. Discovery in the MDL proceeding was separated into multiple phases. The parties completed the first phase of MDL discovery in early 2016. *See* Doc. 519. First-phase MDL discovery included production of documents related to an FDA inspection and Warning Letter, an updated production of complaint (adverse event) files, and an updated version of Bard's complaint database relating to the Recovery, G2, G2X, G2 Express, Eclipse, Meridian, and Denali Filters. *See* Doc. 249. Plaintiffs also conducted a Rule 30(b)(6) deposition concerning the FDA inspection and Warning Letter, and a deposition of corporate witness, Kay Fuller.

The parties completed the second phase of MDL discovery for common fact discovery in February 2017. CMO No. 8, entered on February 2, 2016 (Doc. 519), set deadlines for the second phase of discovery in the MDL proceeding, which included all common fact and expert issues in the MDL, but not case-specific issues to be resolved in individual cases after remand. *See* Docs. 249, 519. Second-phase MDL discovery specifically included extensive additional discovery related to Bard's system architecture for ESI, Bard's ESI collection efforts, Bard's national and regional sales and marketing practices, and ESI relating to Bard's IVC filters. Plaintiffs also deposed two corporate witnesses in connection with the allegations that Kay Fuller had made on national television that a submission to the FDA regarding the Recovery Filter did not bear her original signature after she declined to sign it because of her concerns about the filter. *See* Doc. 1319. Plaintiffs further deposed additional corporate witnesses concerning the FDA inspections and Warning Letter. *See* Doc. 1319.

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Bard also produced discovery regarding the sales and marketing materials related to the Simon Nitinol Filter ("SNF"), documents comparing filter performance and failure rates to the SNF, and internal and regulatory communications relating to the SNF. *See* Docs. 1319, 10489. The Court denied Plaintiffs' request to obtain ESI discovery from Bard's overseas operations. *See* Doc. 3398. The Court denied Bard's request to obtain discovery of communications between Plaintiffs' counsel and NBC related to NBC news stories about the products at issue in this litigation, and third-party financing that may be in place with respect to Plaintiffs in this MDL. *See* Docs. 3313, 3314. Plaintiffs were required to produce communications between Plaintiffs and the FDA related to the FDA Warning Letter, but the Court denied Bard's request to depose Plaintiffs' Counsel regarding these communications. *See* Docs. 3312, 4339. Bard also produced punitive damages discovery, and Plaintiffs conducted a Rule 30(b)(6) deposition related to punitive damages.

1. Document Discovery

Plaintiffs have conducted extensive document discovery against Bard. Document discovery in these cases has now been completed. The Court entered the parties' stipulated ESI protocol. *See* Doc. 519. CMO No. 9, entered on March 31, 2016 (Doc. 1259), governed the production of ESI and hard-copy, paper documents. Bard has produced over 8 million pages of documents from over 100 custodians in this litigation.

2. Depositions of Generic Fact Witnesses

Plaintiffs have conducted extensive deposition discovery against Bard. General fact witness discovery in these cases has now been completed. Prior to establishment of this MDL, approximately 80 witnesses were deposed in connection with this litigation. CMO No. 8 (Doc. 519) established a procedure concerning re-deposing these witnesses in the MDL. CMO No. 14 (Doc. 2239) established deposition protocols generally. The Court allowed additional depositions of several corporate witnesses that had been previously deposed, as well as numerous depositions of other Bard corporate witnesses, including

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several Rule 30(b)(6) depositions. *See* Docs. 3685, 4311. Over 150 depositions of Bard corporate witnesses have been conducted in this litigation.

B. Case-Specific Fact Discovery

The parties did not conduct case-specific fact discovery for the ten mature cases during the MDL proceedings, but instead conducted such discovery in these cases prior to their transfer to the MDL. The Court repeatedly concluded that case-specific discovery in the mature cases should await their remand. *See* Docs. 3214, at 3; 8871 at 5. The status of the remaining case-specific discovery and other pretrial issues for the mature cases being remanded, and the estimated time needed to resolve such issues and make the cases ready for trial, are listed in the attached chart Exhibit "B".

C. Expert Discovery

Plaintiffs have conducted extensive general expert witness discovery against Bard. General expert discovery has now been completed in these cases. The parties designated general experts in all MDL cases, and case-specific experts in individual cases selected for the bellwether process. CMO No. 8, entered on February 2, 2016 (Doc. 519), governed expert disclosures and discovery. General expert discovery closed on July 14, 2017. *See* Doc. 3685. The parties conducted expert discovery in some of the mature cases prior to their transfer to the MDL. The status of the remaining case-specific expert discovery, and the estimated time needed to complete such discovery and make the cases ready for trial, is listed in the attached chart Exhibit B.

D. Privileged Materials

CMO No. 2, entered on October 30, 2015 (Doc. 249), required Bard to provide to Plaintiffs all privilege logs in compliance with the Federal Rules of Civil Procedure. The parties were then required to engage in an informal privilege log meet and confer process to resolve any privilege disputes. Bard produced several privilege logs identifying documents withheld pursuant to the attorney-client privilege, the work-product doctrine, and/or other privileges. The parties regularly met and conferred regarding Bard's privilege

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logs and engaged in negotiations regarding certain entries identified by Plaintiffs. As part of that meet and confer process, Bard provided the Plaintiffs with a small number of these identified items for inspection and, in some cases, withdrew certain claims of attorney-client privilege and produced the previously withheld items.

The Court entered CMO No. 3 (Doc. 314) on December 1, 2015, to govern the non-waiver of any privilege and/or work-product protection in this MDL, or in any other federal or state proceeding, pursuant to Federal Rule of Evidence 502(d), from Bard's disclosure or production of the contents or copies of the documents or items on its privilege logs as part of the meet and confer process.

In late 2015, Plaintiffs challenged a substantial number of documents on Bard's privilege log. The parties engaged in an extensive meet and confer process, and Bard produced certain documents pursuant to the Rule 502(d) order (Doc. 314). Plaintiffs moved to compel production of 133 disputed documents. The Court granted the motion in part and denied in part. *See* Doc. 2813. The parties identified several categories of disputed documents and provided sample documents to the Court for *in camera* review. The Court denied Plaintiffs' motion with respect to seven out of the eight categories of documents and found only one of the sample documents in one of the categories to contain unprivileged portions that should be produced. The Court found all other documents protected by the attorney-client privilege and/or work product doctrine. The Court expected the parties to use this ruling as a guide to resolve remaining privilege disputes.

Since this ruling, there have been no further challenges to Bard's privilege logs. Bard continued to provide updated privilege logs throughout the discovery process, and the parties met and conferred to resolve privilege disputes. Privilege issues should not be a concern for any transferor court on remand.

E. Protective Order/Confidentiality

A stipulated protective order (Doc. 269) governing the designation, handling, use, and disclosure of confidential discovery materials was entered in November 2015. CMO

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No. 7, entered on January 5, 2016 (Doc. 401), governed redactions of material from additional adverse event reports, complaint files, and related documents in accordance with the Health Insurance Portability Act of 1996 ("HIPAA") and under 21 C.F.R. § 20.63(f).

In September 2016, to expedite production of ESI from Bard, the parties agreed to a primarily "no-eyes-on" document production as to relevancy while still performing a privilege review for this expedited ESI document production. CMO No. 17, entered on September 14, 2016 (Doc. 3372), modified the protections and requirements in the stipulated protective order (Doc. 269) and CMO No. 7 (Doc. 401) for ESI produced pursuant to this process. CMO No. 17 was amended in November 2016. *See* Doc. 4015.

IV. Activities Completed Before Remand

The cases listed in Exhibit A are ripe for remand, since common fact discovery and expert disclosures in this MDL have been completed, and the Court has ruled on *Daubert* motions and Defendants' summary judgment motion based on preemption.

A. Key Legal and Evidentiary Rulings Affecting Remanded Cases

The Court has ruled on several, significant pretrial issues affecting the remanded cases and provides the following summary of key legal and evidentiary rulings to assist the transferor court in planning further proceedings and trial.

1. Federal Preemption

Bard sought summary judgment on the grounds that Plaintiffs' state claims are expressly preempted by the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360 et seq., and impliedly preempted by the MDA under the Supreme Court's conflict preemption principles. The Court denied Bard's motion. *See* Doc. 8872. Bard has appealed this ruling to the United States Court of Appeals for the Ninth Circuit (No. 18-16349).

The MDA curtails state regulation of medical devices through a provision that preempts state requirements that differ from or add to federal requirements. 21 U.S.C. § 360k. The Bard IVC filters at issue in this litigation, like most medical devices on the market

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today, were cleared for market through section "510k" review, which focuses primarily on equivalence rather than safety and effectiveness. *See* § 360c(f)(1)(A).

The Supreme Court in *Medtronic, Inc. v. Lohr*, held that § 360k does not preempt state law claims directed at medical devices cleared through the 510(k) process because the substantial equivalence review of that process places no federal requirements on a device. 518 U.S. 470, 492-94 (1996). *Lohr* also noted that the "510(k) process is focused on *equivalence*, not safety." *Id.* at 493 (emphasis original). Although the Safe Medical Devices Act of 1990 ("SMDA"), Pub. L. 101-629, did introduce safety and effectiveness considerations into 510(k) review, it did so only comparatively. Thus, *Lohr* remains good law, and clearance of a product under 510(k) usually does not preempt state common law claims. But this does not mean that 510(k) clearance can never result in preemption. Preemption can occur under the 510(k) process only when the FDA has imposed requirements specific to the device in question.

Although the various FDA reviews of Bard filters do appear to have been more extensive than the 510(k) review at issue in *Lohr*, the Court concluded that Bard failed to show that the reviews imposed device-specific requirements as needed for preemption under § 360k. Even if device-specific federal requirements could be ascertained, Bard failed to show (by discussing the specific law of any particular state) that any state law claim is expressly preempted by federal requirements.

The Court further concluded that Plaintiffs' state law claims are not impliedly preempted because, unlike in *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618 (2011), and *Mutual Pharmaceutical Co. v. Bartlett* – U.S. –, 133 S. Ct. 2466, 2476-78 (2013), Bard failed to show that it is impossible to do under federal law what the state laws require. The Court finally concluded that Bard failed to overcome the presumption against preemption that applies to implied preemption cases.

2. Medical Monitoring Class Action

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In May 2016, Plaintiffs' counsel filed a medical monitoring class action, *Barraza, et al. v. C. R. Bard, Inc., et al.*, that was consolidated with the MDL. *See* Doc. 1 (2:16-cv-01374-DGC). Plaintiffs in the *Barraza* action sought class certification for medical monitoring relief on behalf of themselves and classes of individuals who have been implanted with a Bard IVC filter, have not had that filter removed, and have not filed a claim or lawsuit for personal injury related to the filter. The Court denied the motion. *See* Doc. 95 (2:16-cv-01374-DGC).

Plaintiffs class certification motion recognized that only 16 states permit claims for medical monitoring. The Court concluded that individual issues would predominate if the classes were certified, and therefore they could not be certified under Federal Rule of Civil Procedure 23(b)(3).[3] The Court also concluded that the medical monitoring relief Plaintiffs sought primarily constituted monetary rather than injunctive relief, and therefore could not be certified under Federal Rule of Civil Procedure 23(b)(2). The Court further concluded that Plaintiffs could not show typicality under Federal Rule of Civil Procedure 23(a)(3). Plaintiffs ultimately dismissed their claims without prejudice. *See* Docs. 106, 107 (2:16-cv-01374-DGC).

3. Privilege Ruling relating to the Lehmann Report

The Court granted Bard's motion for a protective order to prevent Plaintiffs from using the December 15, 2004 report of Dr. John Lemann. *See* Doc. 699. Dr. Lehmann was a consultant who provided different services to Bard at different times. Following Bard's receipt of potential product liability claims involving the Recovery Filter, Bard's Law Department retained Dr. Lehmann as a consultant in November 2004 to provide a broad assessment of the risks associated with Bard's Recovery Filter to assist the Law Department

[3] These individual issues would arise from several key elements of Plaintiffs' claim: (1) whether Bard was negligent in the design of various generations of filters; (2) whether Bard was negligent in failing to disclose risks for various kinds of filters at various points in time, given what was known about the risks at the time; (3) whether the learned intermediary defense applies; (4) whether contributory or comparative negligence or assumption of risk apply; (5) whether the proposed medical monitoring is necessary and distinct from the ordinary course of treatment the class member is receiving; and (6) what state's law should apply to each class member's claim.

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in advising Bard on the extent of its legal exposure. Dr. Lehmann prepared a written report of his findings at the request of the Law Department and in anticipation of litigation. The Court found that the report is protected from disclosure by the work product doctrine, Plaintiffs did not show a substantial need for the Report, or that they would experience an undue hardship in obtaining substantially equivalent information, and Bard did not waive the work product protection. The Court agreed with the parties that this ruling should not affect any prior rulings on this issue in cases where the issue has previously been decided.

4. *Daubert* Rulings

The Court has ruled on numerous of the parties' *Daubert* motions and refers the transferor court to the following orders to assist in preparing for trial:

***Daubert* Motion**	**Doc. No(s).**
Order on Motion to Exclude Opinions of Plaintiffs' Expert Dr. Rebecca Betensky	9773
Order on Motion to Exclude Opinions of Plaintiffs' Expert Mark Eisenberg	9770
Order on Motion to Exclude Opinions of Plaintiffs' Experts Drs. David Garcia and Michael Streiff	10072
Order on Motion to Exclude Opinions of Bard's Expert Dr. Clement Grassi	9991, 10230
Order on Motion to Exclude Opinions of Plaintiffs' Expert Dr. David Kessler	9433
Order on Motion to Disqualify Plaintiffs' Expert Dr. Thomas Kinney	9428, 10323 at 4.
Order on Motion to Exclude Opinions of Plaintiffs' Experts Drs. Thomas Kinney, Anne Christine Roberts, and Sanjeeva Kalva	9434

Order on Motion to Exclude Opinions of Plaintiffs' Expert Dr. Robert McMeeking	10051
Order on Motion to Exclude Opinions of Bard Expert Dr. Christopher Morris	10230, 10231
Order on Motion to Exclude Opinions of Plaintiffs' Expert Dr. Derek Muehrcke	9771
Order on Motion to Exclude Opinions of Plaintiffs' Expert Dr. Darren Hurst	9772
Order on Motion to Exclude Opinions of Plaintiffs' Expert Dr. Suzanne Parisian	9433
Order on Motion to Disqualify Plaintiffs' Experts Drs. Scott Resnick, Robert Vogelzang, Kush Desai, and Robert Lewandowski	9432

5. Motions *in Limine*

The Court has made several, significant *in limine* rulings affecting the remanded cases and provides the following summary of key rulings to assist the transferor court in planning further proceedings and trial:

i. FDA Evidence ("*Cisson* Motion")

Plaintiffs sought to exclude, under Federal Rules of Evidence 402 and 403, evidence of FDA 510(k) clearance of Bard IVC filters, and the lack of FDA enforcement action against Bard. The Court denied the motion. *See* Docs. 9881, 10323 at 2-3.

The Court concluded that evidence of Bard's compliance with the 510(k) process, while certainly not dispositive, is nonetheless relevant to the reasonableness of Bard's conduct, whether Bard defectively designed its IVC filters, and whether Bard acted with conscious indifference to the dangers posed by its device. For these reasons, the evidence was relevant to Plaintiff's design defect and punitive damages claims under Georgia law, which was the controlling substantive law for the first two bellwether trials. Even though

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the 510(k) process focuses on device equivalence, not device safety, this does not render evidence of the 510(k) process irrelevant to the reasonableness of Bard's conduct.

The Court also concluded that the probative value of the evidence was not substantially outweighed by the risk of confusing the jury as to whether Bard filters were found by the FDA to be safe and effective; nor would its admission result in mini-trials. The Court believed that such concerns can be adequately addressed without excluding relevant evidence to the detriment of Defendants, if necessary, by a limiting instruction regarding the nature of the 510(k) process, and by efficient management of the evidence and adherence to the Court's time limits for trial. The Court did not find this limiting instruction necessary in either of the *Booker* or *Jones* bellwether trials. *See* Trial Tr. Day 11, at 2447:18-19, *Booker v. C. R. Bard, Inc., et al.* (D. Ariz. Mar. 29, 2018).

The Court further noted that the absence of any evidence regarding the 510(k) process would run the risk of confusing the jury as well, as many of the relevant events in this litigation occurred in the context of FDA 510(k) review, and are best understood in that context. Nor was the Court convinced that all FDA-references could adequately be removed from the evidence.

The Court lastly concluded that it would not exclude evidence and arguments by Bard that FDA took no enforcement action against it with respect to the G2 or Eclipse Filters, or evidence regarding the information Bard provided to the FDA in connection with the 510(k) process. *See* Doc. 10323 at 2-3 (*Booker*); 11011 at 4-5 (*Jones*). The Court concluded that the evidence was relevant to Plaintiff's negligent design and punitive damages claims under Georgia law, which was the controlling substantive law for the first two bellwether trials. Furthermore, the Court ultimately determined at trial that it had no basis to conclude that FDA's lack of enforcement was intended by the FDA as an assertion, and thus should not be barred as hearsay. *See* Trial Tr. Day 8, at 1681:1-6, *Booker v. C. R. Bard, Inc., et al.* (D. Ariz. Mar. 26, 2018).

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ii. FDA Warning Letter

Bard sought to exclude, under Federal Rules of Evidence 402 and 403, evidence of the July 13, 2015 FDA Warning Letter issued to Bard. The Court granted the motion in part excluding as irrelevant topics 1, 2, 4(a), 4(b), 5, 6, 7, and 8 of the warning letter. *See* Doc. 10258 at 6-8; Doc. 10805. Topics 1 and 2 concern the Recovery Cone retrieval system; Topic 4(a) concerns the filter cleaning process; and Topics 4(b), 5, 6, 7, and 8 concern the Denali Filter. The Court concluded that none of these topics were relevant to the issues in the first two bellwether cases involving a G2 Filter (*Booker*) and Eclipse Filter (*Jones*).

The Court found that topic 3, however, concerning Bard's complaint handling and reporting of adverse events with respect to the G2 and Eclipse Filters, as well as the adequacy of Bard's evaluation for the root cause of the violations, was relevant to rebut the implication at trial that FDA never took any action with respect to Bard's IVC filters. *See* Trial Tr. Day 9, at 1888:21 to 1892:25, *Booker v. C. R. Bard, Inc., et al.* (D. Ariz. Mar. 27, 2018); Doc. 11256. The Court also concluded that the Warning Letter is admissible under Federal Rule of Evidence 803(8), and thus should not be barred as hearsay. The Court further concluded that the probative value of topic 3 is not substantially outweighed by the danger of unfair prejudice to Bard. The Court ultimately admitted the Warning Letter in redacted form during the first two bellwether trials. *See* Docs. 10565 (*Booker*), 11256 (*Jones*).

iii. Recovery Filter Cephalad Migration Death Evidence

Bard sought to exclude, under Federal Rules of Evidence 402 and 403, evidence of cephalad migration (i.e., migration of the filter toward the patient's heart) by a Recovery Filter resulting in patient death. The Court denied the motion for the *Booker* bellwether trial (G2 Filter). *See* Doc. 10258 at 4-5; Doc. 10323 at 4. Bard has appealed this ruling to the United States Court of Appeals for the Ninth Circuit (No. 18-16349). The Court repeatedly granted the motion for the *Jones* bellwether trial (Eclipse Filter), denying Plaintiff Jones' repeated attempts to seek reconsideration of the ruling before and during the trial. *See* Docs.

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10819, 10920, 11041, 11113, 11256, 11302; *see also* Trial Tr. Day 10, at 2224:3 to 2226:24, *Jones v. C. R. Bard, Inc., et al.* (D. Ariz. May 30, 2018). Plaintiff Jones has appealed to the United States Court of Appeals for the Ninth Circuit (No. 18-16461).

The Court concluded for purposes of the first bellwether trial (*Booker*) involving a G2 Filter, that evidence of cephalad migration by a Recovery Filter resulting in patient death was necessary for the jury to understand the issues that prompted creation and design of the G2 Filter, and thus was relevant to Plaintiff's design defect claim. *See* Doc. 10323 at 4.[4] The Court also concluded that such evidence was relevant in responding to Bard's assertion that FDA's 510(k) clearance of the G2 Filter amounted to a determination that the G2 was as safe and effective as the Recovery Filter. The Court was concerned, however, that too heavy an emphasis on deaths caused by cephalad migration of the Recovery Filter – a kind of migration which did not occur in Ms. Booker's case – would result in unfair prejudice that substantially outweighs the probative value of the evidence.

The Court concluded for purposes of the second bellwether trial (*Jones*) involving an Eclipse Filter, that evidence of cephalad migration deaths by the Recovery Filter was inadmissible because it was only marginally relevant in Ms. Jones' case. *See* Docs. 10819, 10920, 11041, 11113, 11256, 11302. This is because cephalad migration did not continue in any significant degree beyond the Recovery Filter; cephalad migration deaths all occurred before the Recovery Filter was taken off the market in late 2005; the deaths said nothing about three of Ms. Jones' four claims: strict liability design defect, strict liability

[4] After the *Booker* bellwether trial, the Court later found that changes Bard made in response to cephalad migration largely eliminated that direction of migration in the G2 and later filters. *See* Docs. 10819, 10920, 11041. Counsel for Plaintiff agreed that there has been very little cephalad migration after the Recovery Filter, in part because the G2 Filter was given a wider design to correct the cephalad migration problem. *See* Doc. 10920. The Court's notes from the *Booker* trial reflect that Plaintiff identified only one instance of cephalad migration by a G2 Filter. *See* Doc. 10819. Even after a review of thousands of complaints in Bard's Trackwise database, Plaintiffs provided evidence of cephalad migration by one G2 and three G2X filters out of approximately 180,000 (according to Bard) G2 and G2X Filters sold. *See* Doc. 10920. Counsel was not able to identify any instance of cephalad migration causing death in the G2 or later filters. Thus, the Court concluded that cephalad migration deaths stopped after the Recovery Filter, and that cephalad migrations largely ceased due to changes made to the G2-line of filters.

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failure-to-warn, or negligent failure-to-warn; although the evidence may add some weight to her fourth claim – negligent design – it is not central to proof of design negligence; and instances of cephalad migration resulting in death are not substantially similar to complications experienced by Ms. Jones and therefore do not meet the Georgia standard for evidence on punitive damages. *See* Docs. 10819, 11041.

The Court also found that deaths caused by a non-predicate device, and by a form of migration that was eliminated years earlier, are of sufficiently limited probative value that their relevancy is substantially outweighed by the danger of unfair prejudice because the death evidence may prompt a jury decision based on emotion. Therefore, the Court concluded that this evidence is inadmissible under Rule 403. The Court further concluded that Ms. Jones would not be seriously hampered in her ability to prove Recovery Filter complications, testing, and design when references to cephalad migration deaths are removed. *See* Doc. 11041. As a result, the Court held that such references should be redacted from evidence to be presented at the *Jones* bellwether trial. The Court repeatedly affirmed this ruling during the *Jones* bellwether trial. *See* Docs. 11113, 11302; Trial Tr. Day 10, at 2224:3 to 2226:24, *Jones v. C. R. Bard, Inc., et al.* (D. Ariz. May 30, 2018).

iv. Simon Nitinol Filter Complication Evidence

Plaintiffs sought to exclude evidence of complications associated with Bard's SNF on the grounds that Plaintiffs were barred from conducting relevant discovery into the design and testing of the SNF under CMO No. 10 (Doc. 1319). The Court denied the request. *See* Doc. 10489.

The Court disagreed that Plaintiffs were foreclosed from obtaining relevant evidence for rebuttal. The Court foreclosed this discovery because Plaintiffs did not contend then, and does not contend now, that the SNF is defective. The Court could not see, and Plaintiffs did not explain, how discovery into the design and testing of the SNF would have produced any information on failure rates the SNF experienced after it was on the market. Plaintiffs also had rebuttal evidence showing that reported failure rates for SNF were lower than

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Recovery and G2 Filter rates. The Court ultimately concluded it would not preclude Bard from presenting its SNF evidence on the basis of a discovery ruling and invited Plaintiffs to make appropriate evidentiary objections at trial.

v. Use of Deposition Testimony of Withdrawn Bard Experts at Trial

Defendants sought to preclude, under Federal Rules of Evidence 804 and 403, Plaintiffs' use at trial of the depositions of three defense expert witnesses, Drs. Moritz, Rogers, and Stein, who originally were retained by Bard but have since been withdrawn in some or all cases. The Court denied the request in part. *See* Doc. 10382.

The Court found that Bard failed to show that the depositions are inadmissible on hearsay grounds, but also agreed that it would be unfairly prejudicial under Rule 403 to disclose to the jury that the experts originally were retained by Bard. Therefore, the Court concluded that Plaintiffs may use portions of the experts' depositions that support Plaintiffs' case, but may not disclose to the jury, through argument or deposition excerpts, that the experts originally were retained by Bard. Additionally, the Court was concerned about the presentation of cumulative evidence, and required Plaintiffs to first show "that no other expert of similar qualifications is available or that the unavailable expert has some unique testimony to contribute," before the deposition of any withdrawn expert may be used at trial.

vi. Other *in Limine* Rulings

The Court's other *in limine* rulings (Docs. 10075, 10235, 10258, 10947) may be useful in other jurisdictions, and the Court refers the transferor court to the following orders to assist in preparing for trial:[5]

- **Parties' (*Booker*) Joint Stipulation on Motions *in Limine*:** The Court, by stipulation of the parties, excluded evidence, argument, and testimony

[5] The Court also ruled on the parties' motions *in limine* concerning several case-specific issues. *See* Docs. 10075 (Plaintiffs' (*Booker*) MIL No. 12), 10258 (Plaintiffs' (*Booker*) MIL Nos. 6, 13), 10947 (Bard's (*Jones*) MIL No. 1; Plaintiffs' (*Jones*) MIL Nos. 1-4, 7).

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concerning several case-specific issues in the *Booker* bellwether trial, as well as a few general issues, including: C. R. Bard, Inc.'s 1994 criminal conviction; other lawsuits or claims against Bard; and advertising by Plaintiff's counsel, Plaintiff's counsel specializing in personal injury and/or products liability litigation, contingency fee agreements, and/or advertising by any counsel nationally for Bard IVC filter cases and/or any other IVC filter cases. *See* Doc. 10235.

- **Bard's (*Booker*) MIL No. 1:** The Court permitted evidence and testimony concerning Recovery Filter complications. *See* Doc. 10258; *see also* Doc. 10819 (*Jones*). As noted above, the Court permitted evidence and testimony concerning Recovery Filter cephalad migrations resulting in patient death in the *Booker* bellwether trial involving a G2 Filter (Doc. 10323 at 4), but excluded such evidence in the *Jones* bellwether trial involving an Eclipse Filter. *See* Docs. 10819, 10920, 11041.

- **Bard's (*Booker*) MIL No. 2:** The Court permitted evidence and testimony relating to the development of the Recovery Filter. *See* Docs. 10258; *see also* Doc. 10819 (*Jones*).

- **Bard's (*Booker*) MIL No. 4:** The Court excluded evidence and testimony concerning a photograph of Michael Randall pointing his middle finger at the camera. *See* Doc. 10075.

- **Bard's (*Booker*) MIL No. 5:** The Court permitted Plaintiff's Expert Dr. Thomas Kinney to be called as a fact witness, but prohibited him from testifying regarding his prior work for Bard as an expert witness in two prior IVC filter cases or as a paid consultant to Bard for several years. *See* Docs. 10075, 10323 at 4.

- **Plaintiffs' (*Booker*) MIL No. 2:** The Court reserved ruling until trial on evidence and testimony regarding the nature of Bard's business, including the nature,

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quality, and usefulness of its products, the conscientiousness of its employees, references to its mission statement, and the fact that its products are designed to promote health and save lives. *See* Doc. 10075.

- **Plaintiffs' (*Booker*) MIL No. 3:** The Court permitted evidence and testimony concerning the benefits of IVC filters, including testimony describing Bard filters as "lifesaving" devices. *See* Doc. 10258.

- **Plaintiffs' (*Booker*) MIL No. 4:** The Court permitted evidence and testimony that IVC filters, including Bard's filters, are within the standard of care for the medical treatment of pulmonary embolism. *See* Doc. 10258. Bard stated it would not characterize IVC filters as the "gold standard" for the treatment of pulmonary embolisms.

- **Plaintiffs' (*Booker*) MIL No. 5:** The Court denied as moot Plaintiff's motion to exclude evidence and argument relating to failure rates, complication rates, percentages, or comparative analysis of any injuries that were not produced to Plaintiffs during discovery, as all such information was produced. *See* Doc. 10075.

- **Plaintiffs' (*Booker*) MIL No. 7:** The Court excluded evidence and argument relating to prior judicial opinions about Plaintiffs' experts, including the number of times their testimony has been precluded in other cases. *See* Doc. 10075.

- **Plaintiffs' (*Booker*) MIL No. 8:** The Court excluded evidence and argument that a verdict against Bard will have an adverse impact on the medical community, future medical device research or costs, and the availability of medical care. *See* Doc. 10075.

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- **Plaintiffs' (*Booker*) MIL No. 9:** The Court deferred ruling on the relevance of statements or lack of statements from medical societies, including the Society of Interventional Radiologists ("SIR"), until trial. *See* Doc. 10258. The Court ultimately admitted this evidence in both the *Booker* and *Jones* bellwether trials.

- **Plaintiffs' (*Booker*) MIL No. 10:** The Court excluded evidence and testimony that Bard needed FDA consent to add any warning to its labels, send warning letters to physicians and patients, or recall its filters. *See* Doc. 10258. The Court permitted evidence and argument explaining the reasons why Bard filters were not recalled, FDA's potential involvement in any recall effort, and the fact that warnings about failure rates and increased risks could not be based on MDR and MAUDE data alone.

- **Plaintiffs' (*Booker*) MIL No. 11:** The Court permitted evidence and argument relating to the informed consent form signed by the Plaintiff prior to insertion of the IVC filter, even though the form is not specific to IVC filters or Bard filters. *See* Doc. 10075.

- **Plaintiffs' (*Booker*) MIL No. 14:** The Court reserved its ruling until trial on evidence and argument relating to certain background information and personal traits of Bard employees and witnesses. *See* Doc. 10075.

- **Bard's (*Jones*) MIL No. 2:** The Court excluded evidence and testimony of other lawsuits against Bard. *See* Doc. 10947.

- **Plaintiffs' (*Jones*) MIL No. 5:** The Court excluded evidence and testimony that Bard employees or their relatives have received Bard IVC filter implants. *See* Doc. 10947.

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- **Plaintiffs' (*Jones*) MIL No. 6:** The Court permitted evidence and testimony concerning whether a parties' expert had been retained by the same attorneys in other litigation. *See* Doc. 10947.

6. Deposition Designations

The Court has ruled on numerous of the parties' objections to deposition designations for trial and refers the transferor court to the following orders[6] to assist in preparing for trial:

Deponent	Depo. Date	Doc. No(s).
Bill Altonaga	10/22/2013	10497, 10922
Christine Brauer	05/23/2014 08/02/2017	10922, 10922
David Ciavarella	11/12/2013	10403
Gary Cohen	01/25/2017	10438
Robert Cortelezzi	11/11/2016	10438, 11064
Len DeCant	05/24/2016	10438, 11080
John DeFord	06/02/2016	10524, 11080
Mary Edwards	01/20/2014	10438
Robert Ferrara	04/17/2017	10438
Chris Ganser	10/11/2016	10438, 11073
Jason Greer	08/11/2014	10438, 10922
Janet Hudnall	11/01/2013	10403
Brian Hudson	01/17/2014	10403
John Lehmann	08/07/2014	10922

[6] In addition to the depositions identified in the table above, the Court also ruled on numerous objections to case-specific deposition designations for trial.

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Deponent	Depo. Date	Doc. No(s).
William "Bill" Little	07/27/2016	10438, 11064
John McDermott	02/05/2014	10438
Patrick McDonald	07/29/2016	10486, 11064
Mark Moritz	07/18/2017	10922
Daniel Orms	08/16/2016	10403, 11073
Abithal Raji-Kubba	07/18/2016	11064
Gin Schulz	01/30/2014	10403
Christopher Smith	08/03/2017	11073
William Stavropoulos	02/01/2017	10524
Jack Sullivan	11/03/2016 09/16/2016	10486, 11080
Melanie Sussman	04/07/2017	11073
Mehdi Syed	03/02/2018	11313
Scott Trerotola	01/20/2017	10524
Douglas Uelmen	10/04/2013	10403, 11080
Carol Vierling	05/11/2016	10486, 11073
Mark Wilson	01/31/2017	10922
Natalie Wong	10/18/2016	10403

V. Further Proceedings Needed in Remand Courts

A. General Discovery

All general fact and expert discovery in these cases has been completed before remand. Therefore, transferor courts need not be concerned with facilitating general expert, corporate, and third-party discovery.

B. Case-Specific Discovery and Trial Preparation

According to the parties, the status of the remaining discovery and other pretrial issues for the cases being remanded, and the estimated time needed to resolve such issues

and make the cases ready for trial, are listed in the attached chart Exhibit B. Final trial preparation in the bellwether trials was governed by Court orders. *See* Docs. 8871, 10323, 10587, 11011, 11320, 11321.

VI. Documents to be Sent to Transferor Court

After receiving the Final Remand Order ("FRO") from the JPML, the Clerk of the Court will issue a letter to the transferor courts, via email, setting out the process for transferring the individual cases listed in the FRO. The letter and certified copy of the FRO will be sent to the transferor's court's email address.

If a party believes that the docket sheet for a particular case being remanded is not correct, a party to that case may, with notice to all other parties in the case, file with the transferor court a Designation Amending the Record. Upon receiving a Designation Amending the Record, the transferor court may make any needed changes to the docket. If the docket is revised to include additional documents, the parties should provide those documents to the transferor court.

RESPECTFULLY SUBMITTED this 13th day of August, 2018.

s/Richard B. North, Jr.
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CERTIFICATE OF SERVICE

I hereby certify that on this 13th day of August 2018, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all attorneys of record.

s/Richard B. North, Jr.
Richard B. North, Jr.

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